SEP 6 2012 K112892

Impella 2.5 Plus 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807.92.

A. Application Information:

Date Prepared: September 5, 2012

Submitter's Name & Address:
ABIOMED, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Contact Person:
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B. Device Information:

Trade or Proprietary Name: Impella 2.5 Plus
Common or Usual Name: Non-roller type Cardiopulmonary Blood Pump
Classification Name: Class III, KFM, 21 CFR - 870.4360
Performance Standard: Performance standards do not currently exist for these devices. (i.e. none established under section 514 of the F D & C Act.)

C. Predicate Device:

The IMPELLA 2.5 (K063723)

D. Device Description:

The Impella 2.5 Plus is an update to the design of the IMPELLA 2.5, which was cleared by the FDA in 2008 (under K063723). The predicate device, the IMPELLA 2.5, and the Impella 2.5 Plus have identical designs and materials of construction. The only design modifications made to the IMPELLA 2.5 for the Impella 2.5 Plus are slight increases in the diameters of the inflow cannula, impeller and pump housing (from 12 F to 14 F). As a result of this increase, the Impella 2.5 Plus has approximately 30% higher flow than the IMPELLA 2.5.

E. Intended Use:

The Impella 2.5 Plus is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The Impella 2.5 Plus also provides pressure measurements which are useful in determining intravascular pressure

F. Technological Characteristics:

The Impella 2.5 Plus design is a straight-forward iteration (scale-up) of the IMPELLA 2.5 design. The Impella 2.5 Plus employs identical functional scientific technology as the IMPELLA 2.5. The design modifications associated with the Impella 2.5 Plus (i.e. related to the IMPELLA 2.5):

- do not affect the intended use of the device, AND
- do not alter the fundamental scientific technology of the device.

G. Comparison to Predicate Device:

The Table below provides a comparison of the overall design properties of the Impella 2.5 Plus to the predicate IMPELLA 2.5.

Design Specifications Comparison Table

Design Property	**Impella 2.5 Plus**	**IMPELLA 2.5 (K063723)**
Drive console	IMPELLA Controller (identical to that cleared under (K110845)	
Insertion Method	Percutaneous via the Seldinger technique.	
Packaging	Polystyrene tray in double Tyvek Pouch	
Sterilization	Ethylene Oxide (EtO)	
Drive catheter, Size, (Material)	Contains drive line, pressure lumen, purge lumen, 9F, (Polyurethane)	
Seal (Purge Fluid)	Fluid Bearing (Dextrose solution with Heparin)	
Purge Fluid Rate	2-30 cc/hr	
Mean Flow	Up to 3.3 L/Min (60 mmHg differential pressure)	Up to 2.5 L/Min (60 mmHg differential pressure)
Pump Speed	46,0000 RPM	51,0000 RPM
Pump type/ Design, Diameter	Rotary axial flow pump/ Axial inflow, tangential outflow, 14F.	Rotary axial flow pump/ Axial inflow, tangential outflow, 12F.
Motor Design, Diameter	Hydrodynamic bearing with an integral stator winding,14F	Hydrodynamic bearing with an integral stator winding, 12F
Cannula/ Pigtail tip (Material)	14 F inflow cannula with 6F pigtail (Polyurethane)	12 F inflow cannula with 6F pigtail (Polyurethane)

H. Summary of Performance Data:

The Impella 2.5 Plus was developed under design controls. Testing was completed to mitigate any possible new risks from the minor design differences (from the predicate IMPELLA 2.5), and to verify the Impella 2.5 Plus met its design requirements. Testing included:

- Design and Verification & Validation (DVV) testing, which demonstrated that the Impella 2.5 Plus operated as intended and was substantially equivalent to the IMPELLA 2.5.
- Software Verification testing was also completed to verify the Impella 2.5 Plus could be used with the IMPELLA Controller.
- Electrical Standards and Safety testing (IEEC 60601-1, Applied Part) was completed to verify compliance for use of the Impella 2.5 Plus with the IMPELLA Controller.

The results of the bench testing demonstrated that the design changes associated with the Impella 2.5 Plus did not raise any issues related its safety or effectiveness compared to its predicate, the IMPELLA 2.5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP - 6 2012

Abiomed, Inc.
c/o Ms. Carolyn Pekar
22 Cherry Hill Drive
Danvers, MA 01923

Re: K112892
Trade Name: IMPELLA 2.5 PLUS Catheter
Regulation Number: 21CFR 870.4360
Regulation Name: Non-roller type cardiopulmonary bypass blood pump
Regulatory Class: Class III (three)
Product Code: PBL
Dated: September 29, 2011
Received: September 30, 2011

Dear Ms. Pekar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the] device's labeling:

> The safety and effectiveness of this device has not been established for use in providing partial or full support of the blood circulation for periods of greater than 6 hours, or for

providing prophylactic hemodynamic support, for example, in patients with stable hemodynamics during percutaneous interventional procedures of high risk coronary artery lesions and/or anatomy.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112892

Device Name: IMPELLA 2.5 PLUS

Indications For Use:

The IMPELLA 2.5 PLUS Catheter is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The IMPELLA 2.5 PLUS Catheter also provides pressure measurements which are useful in determining intravascular pressure.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112892